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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,243	12/27/2001	Karen L. Fearon	377882001800	8533

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,243	FEARON ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,24 and 26-48* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 27-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 9-21, 24, 26, 47 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 1-4-06 has been entered into the record. Claims 22-23 and 25 have been cancelled. Claims 1-21, 24 and 26-48 are pending. Claims 1-4, 9-21, 24 and 26, 47+48 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claims 5-8 and 27-46 drawn to an invention nonelected with traverse in the response filed 3-2-05. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections Withdrawn

The objection to claims 9-25, 47 and 48 as alternatively drawn to non-elected subject matter.

The rejection of claims 1-4, 9-19, 22-26 and 47 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The rejection of claims 1-3, 7, 9, 11, 15, 16, 17, 18, 19 and 22 under 35 U.S.C. 102(b) as being anticipated by Jefferson et al (US Patent No. 5,879,906, issued March 9, 1999) is withdrawn in view of the amendments to the claims.

Rejections Maintained

Claims 9-21 and 48 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons made of record in the Office Action mailed 8-1-05.

Applicants' arguments have been considered but are not persuasive. Applicants argue that the fact that a mechanism of action may be known or not known is not the test for compliance with written description. This is not persuasive, the fact remains that the specification as filed does not provide for description of any nucleic acid that functions to down regulate an immune response and as such, the skilled artisan would clearly recognize that Applicants were not in possession of "immunomodulatory polynucleotides" in view of the disclosure of only immunostimulatory polynucleotides. Applicants amendments obviated the rejection as applied to claims 1, 2, 3, 4, 26 and 47. The issue still remains with respect to dependent claims 9-21 and 48.

Claims 1-4, 9-21, 24, 26 and 47-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated immunostimulatory oligodeoxynucleic acids consisting of SEQ ID NOs:18, 38 and 59, wherein the immunostimulatory polynucleotide is fully modified phosphorothioate oligodeoxynucleotides and said immunostimulatory oligodeoxynucleic acids increase IFN-gamma or IFN-alpha and compositions comprising such and wherein the immunostimulatory nucleic acid is optionally complexed with cationic poly(lactic acid, glycolic acid) microspheres, it does not reasonably provide enablement for immunomodulatory nucleic acids, immunostimulatory nucleic acids in general, and biodegradable microcarriers in general, or oligoriboxynucleotides, immunostimulatory sequences liked to cationic poly(lactic acid, glycolic acid) by any means or biodegradable carriers in general is maintained for reasons made of record in the Office Action mailed 8-1-05.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that they teach how to make and use the claimed invention without undue experimentation. This is not persuasive for the reasons made of record in the Office Action mailed 8-1-05. It is noted that "immunostimulatory" is discussed in the specification to encompass measureable immune response such as antigen-specific antibody

production, secretion of cytokines, activation or expansion of lymphocyte populations such as NK, CD4+, CD8+ T lymphocytes, B lymphocutes and preferably preferentially activate a Th1-response (page 11 of specification). Applicants reiterate the broad teachings of the specification in conjunction with assays designed to pick out among the vast claimed genus, those that may be potentially useful. The issue here is make and use, and not make and test in an assay to see if you can potentially use. In applications directed to inventions in arts but where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. In the instant case, the specification does not provide for the full scope of "imunostimulatory" in regard to the claimed nucleic acids. Applicants argue that the fact that the source of the interferons is not taught by the specification does not support a finding of non-enablment. This is not persuasive, the rejection of record is not based solely upon questioning the source of the interferon. The rejection is based on the concepts as provided in the specifications as it relates to Applicants own concept of what is encompassed by the term "ISS" as set forth in the specification in view of the Wands factors. Applicants aruge that the claimed invention does not recite generation of a Th1-response. This is not persuasive, Applicants own definition of ISS in the specification teaches this. The scope of the terms of the claims are interpreted in light of the specification. As such, clearly the claims encompass this embodiment. Applicants argue that the examples provide for in vitro and in vivo immunomodulatory activity as claimed. This is not persuasive, the examples were limited

as indicated in the office action mailed 8-1-05 and maintained herein as enabled. The examples do not provide enablement for the full scope of ISS, much less the full scope of the generic claims. Applicants argue that the ISS may or may not be modified and as such the lack of showing that a fully modified ISS is effective is not sufficient to question enablement. This is not persuasive, claims 20 and 21 encompass embodiments wherein every bond is stabilized or modified and the evidence of record indicates that backbone modification and length of polynucleic acid impacts the immunostimulatory ability. Applicants argue that the examiner points out that specification teaches that the length of claimed oligonucleotide impacts the ability to produce interferon and that the claimed invention does not require the production of interferon. This is again not persuasive, cytokine production is encompassed by the term "ISS" in the claims and the production of interferon correctly addressed. The term ISS has specific meaning and encompasses specific activities of the polynucleic acid as specifically contemplated by the specification as filed. The art of record set forth the unpredictability of the CpG art and modification of oligonucleotides and use of them to stimulate an immune response either in vitro or in vivo at the time that the invention was made.

The rejection is maintained.

Claims 1-3, 15-19, 26, 48 stand rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al (US Patent No. 6800744, issued October 5, 2004 with priority to provisional document 60/051,533 filed July 2, 1997) is maintained for reasons made of record in the Office action mailed 8-1-05.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that the art does not teach the claimed invention. This is not persuasive, the art teaches fragments and compositions comprising such as set forth in the last office action of record.

New Rejections Based on Amendment

Claims 9-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 9-21, the claims are prima facie indefinite because the term "the immunomodulatory polynucleotide" lacks antecedent basis.

Status of Claims

All examined claims stand rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy
Primary Examiner
Art Unit 1645